REMARKS

The following remarks are made in response to the Final Office Action mailed June 16, 2004. Claims 11-26 have been previously withdrawn from consideration and previously canceled. In addition, in this Response claims 2, 27, 29-30, and 35 have been cancelled. No claims have been allowed. Claims 1-10, 27, 28, 31-34, and 37-43 were rejected. With this Response, claims 1, 28, 36, 37, 40, 41 and 43 have been amended. Claims 1, 3-10, 28, 31-34, and 36-43 remain pending in the application and are presented for reconsideration and allowance.

Claim Rejections under 35 U.S.C. § 112

A. Section 112, First Paragraph

In the Office Action, claims 1-10, 27-28, 31-34, and 36-40 were rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (a new matter rejection).

Regarding the language "target cellular material" in claims 1 and 36, Applicant respectfully submits that this language has overwhelming support in the specification. First, on page 7, paragraph 26, Applicant's specification states that "the process of the present invention is preferably performed in a plurality of specimens each of which contain at least one target cell of interest in order to ascertain the effect of at least one potential pharmaceutically active agent on the cellular material in question" (underlining added). Both the underlined segments in this passage refer to the same thing, and in the first instance, the phrase cell of interest is paired with the word "target". In the second instance, the phrase "cellular material" is paired with the phrase "in question", which undoubtedly also refers to the "target cell of interest". Accordingly, this sentence of Applicant's specification supports the claim language "target cellular material".

This claim language finds additional support in other portions of Applicant's specification. In particular, page 9, paragraph 35 states "Typically substance or substances

containing cellular material are ones which contain particular cells of interest for which evaluation of potential pharmaceutically active material is sought (cited by the Examiner). These cells of interest are typically referred to as target cells (underlining added)."

The underlined language in this cited portion of Applicant's specification directly tracks similar language found in Applicant's specification at page 7, paragraph 26, and also further associates the words "target" with "cellular material" and "cells of interest". This sentence alone also supports the claim language "target cellular material".

Finally, the remaining portion of page 9, paragraph 35 (as well as paragraph 36) of Applicant's specification include additional examples of use of the phrase "target cells of interest", including stating that "the target cells in the biological sample 14 may be present in a carrier media. The carrier media is generally a solid or liquid material in which the target cells are contained." and that "the substance in which the target cells are contained . . ." (underlining added). This last phrase clearly further associates the phrase "target cells" within "substance" as express in Applicant's claims 1 and 36.

For these reasons, Applicant's respectfully submit that the language "target cellular material" is clearly supported in the specification and requests withdrawal of the rejection of claims 1 and 36 under 112.

Regarding the language "the relative effectiveness of the agent on the target cellular material" in claims 1 and 36, Applicant has amended claims 1 and 36 to recite "regarding the pharmacological effect of the at least one potential pharmaceutically active agent on the target cellular material". With this amendment, Applicant believes that claims 1 and 36 comply with Section 112, and therefore, respectfully request withdrawal of the rejection.

Regarding the language "a cartridge that includes an interior chamber defining a fixed volume for containing the potential pharmaceutical active agent" in claims 1 and 36, Applicant has amended claims 1 and 36 to recite "a cartridge that includes a chamber defining a volume for containing the potential pharmaceutical active agent". The word "chamber" is found in association with the term "reservoir" in Applicant's specification at page 12, paragraph 44 through page 13, paragraph 46 which refers to Figure 3 and stating "the cartridge 28' has at least one reservoir containing a pharmaceutically active agent . . . (paragraph 44) and " cartridge 28 contains a diluent or interlayer material and cartridge 28'' contains three different potential pharmaceutically active agents in chambers 29a, 29b, 29c."

(paragraph 45) and "the one-chamber and three-chamber cartridges above are only exemplary . . . "(paragraph 46).

It is apparent that this/these chambers hold volumes of the agent, and all of the language of claims 1 and 36 regarding this phrase are found together in the cited passages. Accordingly, Applicant respectfully submits that Applicant's specification readily supports this language in amended independent claims 1 and 36, and therefore Applicant respectfully requests withdrawal of the rejection.

B. Section 112, Second Paragraph

In the Office Action, claims 1-10, 27-28, 31-34, and 36-43 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

First, Applicant has amended claims 1 and 36 to specify: " wherein the cellular material is whole cells or recognized cellular components from intact cells". This claim phraseology is allowed per MPEP Section 2173(h).

Second, Applicant has amended claims 1 and 36 to replace the phrase "relative effectiveness" with "regarding the pharmacologic effect of the at least one potential pharmaceutically active agent".

For these reasons, Applicant believes that amended independent claims 1 and 36 comply with Section 112, second paragraph, and therefore respectfully request withdrawal of the rejection.

Claim Rejections under 35 U.S.C. § 102

A. Independent Claim 1

In the Office Action, claims 1-10 and 27-30, 31-34 were rejected under 35 U.S.C. § 102(b) as being anticipated by Stylli et al. U.S. Patent No. 5,985,214 (herein Stylli).

Applicant's amended independent claim 1 specifies an automated method for analyzing substances containing cellular material. The method comprises removably receiving a consumable cartridge containing at least one potential pharmaceutically active

agent into a test apparatus with the test apparatus comprising at least one liquid ejection device including the at least one consumable cartridge and an electronically actuated drop-on-demand printhead acting in fluid communication and electronic communication with the at least one consumable cartridge.

The method comprises activating the test apparatus to dispense a first defined volume of the at least one potential pharmaceutically active agent from the drop-on-demand printhead of the at least one liquid ejection device into contact with at least one defined volume of a substance containing a target cellular material wherein the target cellular material is whole cells or recognized cellular components from intact cells. The method also comprises capturing and maintaining information, via a memory storage device of the at least one consumable cartridge, pertaining to at least one of a function of the at least one consumable cartridge and the at least one potential pharmaceutically active agent. The method further comprises detecting in the at least one defined volume of the substance a pharmacological effect on the target cellular material triggered by introduction of the first defined volume of the at least one potential pharmaceutically active agent and generating information indicative of the pharmacological effect of the at least one potential pharmaceutically active agent on the target cellular material. The generated information is analyzed to generate a correlation factor regarding the pharmacological effect of the at least one potential pharmaceutically active agent on the target cellular material.

In contrast, Stylli discloses a system including a storage and retrievable module and a sample distribution module. In the context of a sample distribution module, Stylli discloses a liquid handler which may comprise a plurality of nanoliter dispensers. See Stylii at Column 15, lines 39-68 and Column 16, lines 1-58. There are no Figures in Stylli illustrating the structure or features of the nanoliter dispensers and no Figures illustrating their relationship to other aspects of the modules of Stylli.

The nanoliter dispensers in Stylli do not include a memory storage device. Accordingly, the system in Stylli, particularly the nanoliter dispensers, do not enable capturing and maintaining information, via a memory storage device of an at least one consumable cartridge, pertaining to the at least one potential pharmaceutically active agent or a function of the cartridge, as claimed by Applicant in claim 1.

In Stylli, there is no electronic communication between a nanoliter dispenser and its reservoir from which it receives fluid, and therefore fails to disclose Applicant's claimed method in which the consumable cartridge is removably received into the test apparatus to enable fluid communication and electronic communication between the at least one consumable cartridge and a drop-on-demand printhead.

In addition, the nanoliter dispensers in Stylli (and any reservoir associated with or forming a part of the nanoliter dispensers) are not consumable. Rather, the nanoliter dispensers in Stylli form a permanent part of liquid handler and sample distribution module, and therefore are not consumable and are not removably receivable within a test system, as claimed by Applicant. Moreover, the reservoirs described as part of or in cooperation with the nanoliter dispensers are not consumable. Accordingly, the nanoliter dispensers of Stylli do not describe or suggest Applicant's claimed method of removably receiving into a test apparatus at least one consumable cartridge for containing at least one potential pharmaceutically active agent.

In Applicant's claimed method, the consumable cartridge allows disposal of the cartridge after depletion of agent from the chamber (e.g., reservoir) of cartridge – permitting a single use of the cartridge. This feature helps to maintain sterility of the test apparatus and avoids time-consuming cleaning operations of reservoirs, as would be necessary with the reservoirs of the nanoliter dispensers of Stylli. See Stylli at Col. 16, lines 52-58. Accordingly, in Applicant's method, instead of washing out and rinsing the cartridge, prior to loading more agents/reagents into the cartridge, the empty cartridge is simply removed and a different cartridge containing an agent/reagent is inserted into the test apparatus for fluid communication with the printhead to enable faster resumption of testing. Moreover, the feature of removably receiving the cartridge into the test apparatus permits removing the cartridge even prior to exhaustion of the agent from the chamber so that a different cartridge having a second agent can be inserted into the test apparatus. Accordingly, one can switch agents being dispensed without having to perform a cleaning operation of the cartridge, and one can do so before the chamber (in fluid communication with the printhead) is emptied. Stylli fails disclose such removable reception and/or consumability of its nanoliter dispensers, and particularly their reservoirs.

Applicant's specification describes the replaceable/consumable feature and the removable receiving of these cartridges into the test apparatus at page 6, paragraph 16; page 11, paragraph 39; page 13, paragraphs 44 and 45; and page 17, paragraph 60. Figures 2 and 3 also illustrate the ability to removably receive the replaceable/consumable cartridges.

Finally, one cited passage in the Office Action refers to Column 16, lines 40-44 of Stylli regarding a nanoliter dispenser having a reservoir. However, the embodiment in cited passage does not included a printhead, as claimed by Applicant, but rather a solenoid valve for releasing fluid from a reservoir. This solenoid valve structure is not equivalent to a drop-on-demand printhead claimed by Applicant, and accordingly any portions of this cited passage regarding the relationship of a reservoir to a valve are not applicable to Applicant's claimed method including at least one consumable cartridge having a chamber in fluid communication and electronic communication with a drop-on-demand printhead.

For these reasons, Stylli fails to disclose Applicant's claimed automated method of analyzing substances containing cellular material, and therefore Applicant respectfully submits that Applicant's amended independent claim 1 is allowable over Stylli. Claims 3-10, 28, and 31-34 are also believed to be allowable as well based on their dependency from amended independent claim 1.

B. Independent Claim 36

In the Office Action, claims 36-44 were rejected under 35 U.S.C. § 102(b) as being anticipated by Stylli.

Applicant's independent claim 36 specifies an automated method for analyzing substances containing cellular material. The method comprises removably receiving into a test apparatus at least one liquid ejection device comprising at least one consumable cartridge. The at least one consumable cartridge includes at least one chamber containing at least one potential pharmaceutically active agent, a memory storage device, and an electronically actuated drop-on-demand printhead, in fluid communication with the chamber. The method comprises activating the test apparatus to dispense, via the drop-on-demand printhead, a first defined volume containing the at least one potential pharmaceutically active agent from the at least one liquid ejection device into contact with at least one defined

volume of a substance containing a target cellular material wherein the cellular material is whole cells or recognized cellular components from intact cells.

The method of claim 36 also comprises capturing and maintaining, via the memory storage device of the cartridge, information pertaining to at least one of a function of the cartridge and the at least one potential pharmaceutically active agent contained within the cartridge. The method further comprises detecting in the at least one defined volume a pharmacological effect on the target cellular material triggered by introduction of the first defined volume of the at least one potential pharmaceutically active agent and generating information indicative of the pharmacological effect of the at least one potential pharmaceutically active agent on the target cellular material. The method also comprises analyzing the generated information to generate a correlation factor regarding the pharmacologic effect of the at least one potential pharmaceutically active agent on the target cellular material.

In contrast, Stylli discloses a system including a storage and retrievable module and a sample distribution module. In the context of a sample distribution module, Stylli discloses a liquid handler which may comprises a plurality of nanoliter dispensers. See Stylii at Column 15, lines 39-68 and Column 16, lines 1-58. There are no Figures in Stylli illustrating the structure or features of the nanoliter dispensers and no Figures illustrating their relationship to other aspects of the modules of Stylli.

The nanoliter dispensers in Stylli do not include a memory storage device. Accordingly, the system in Stylli, particularly the nanoliter dispensers, do not enable capturing and maintaining information, via a memory storage device of an at least one consumable cartridge, pertaining to the at least one potential pharmaceutically active agent or a function of the cartridge, as claimed by Applicant in claim 36.

In addition, the nanoliter dispensers in Stylli are not consumable. Rather, the nanoliter dispensers in Stylli form a permanent part of liquid handler and sample distribution module, and therefore are not consumable and are not removably receivable within a test system, as claimed by Applicant. Accordingly, the nanoliter dispensers of Stylli fail to enable removably receiving into a test apparatus at least one liquid ejection device including at least one consumable cartridge.

In Applicant's claimed method, the consumable cartridge allows disposal of the cartridge after depletion of agent from the chamber (e.g., reservoir) of cartridge – permitting a single use of the cartridge. This feature helps to maintain sterility of the test apparatus and avoid time-consuming cleaning operations, as would be necessary with the nanoliter dispensers of Stylli. See Stylli at Col. 16, lines 52-58. Accordingly, in Applicant's method, instead of washing out and rinsing the cartridge, and particularly the printhead, prior to loading more agents/reagents into the cartridge, the empty cartridge is simply removed and a different cartridge containing an agent/reagent is inserted into the test apparatus so that additional testing can begin immediately. Moreover, the feature of removably receiving the cartridge into the test apparatus permits removing the cartridge even prior to exhaustion of the agent from the chamber so that a different cartridge having a second agent can be inserted into the test apparatus. Accordingly, one can switch agents being dispensed without having to perform a cleaning operation, and one can do so before the chamber (in fluid communication with the printhead) is emptied. Stylli fails disclose such removable reception and/or consumability of its nanoliter dispensers.

Applicant's specification describes the replaceable/consumable feature and the removable receiving of these cartridges into the test apparatus at page 6, paragraph 16; page 11, paragraph 39; page 13, paragraphs 44 and 45; and page 17, paragraph 60. Figures 2 and 3 also illustrate the ability to removably receive the replaceable/consumable cartridges.

Finally, one cited passage in the Office Action refers to Column 16, lines 40-44 of Stylli regarding a nanoliter dispenser having a reservoir. However, the embodiment in cited passage does not included a printhead, as claimed by Applicant, but rather a solenoid valve for releasing fluid from a reservoir. This solenoid valve structure is not equivalent to a drop-on-demand printhead claimed by Applicant, and accordingly any portions of this cited passage regarding the relationship of a reservoir to a valve are not applicable to Applicant's claimed method including a consumable cartridge having a chamber in fluid communication with a printhead.

For these reasons, Stylli fails to disclose Applicant's claimed automated method of analyzing substances containing cellular material, and therefore Applicant respectfully submits that Applicant's amended independent claim 36 is allowable over Stylli. Claims 38

and 40 are also believed to be allowable as well based on the dependency of claims 38 and 40 from independent claim 36.

C. Independent Claim 41

Applicant's independent claim 41 specifies an automated method for analyzing substances containing cellular material. The method comprises removably receiving at least one replaceable cartridge containing at least one potential pharmaceutically active agent into a test apparatus. The test apparatus comprises at least one liquid ejection device including the at least one replaceable cartridge and an electronically actuated drop-on-demand printhead acting in fluid communication and electronic communication with the at least one replaceable cartridge. The test apparatus is activated to dispense a first defined volume containing the at least one potential pharmaceutically active agent from the drop-on-demand printhead of the at least one liquid ejection device into contact with at least one defined volume of a substance containing a target cellular material wherein the target cellular material is whole cells or recognized cellular components from intact cells. The method also comprises detecting in the at least one defined volume a pharmacological effect on the target cellular material triggered by introduction of the first defined volume of the at least one potential pharmaceutically active agent and generating a first information indicative of the pharmacological effect of the at least one potential pharmaceutically active agent on the target cellular material. Based upon the generated information, a second defined volume of at least one potential pharmaceutically active agent is interactively dispensed from the at least one liquid ejection device into contact with the at least one defined volume of the substance containing the target cellular material and generating a second information indicative of the effect of the second defined volume of at least one potential pharmaceutically active agent on the target cellular material.

In contrast, Stylli discloses a system including a storage and retrievable module, a sample distribution module, and a reaction module, among other things. In the context of a sample distribution module, Stylli discloses a liquid handler which may comprises a plurality of nanoliter dispensers. See Stylii at Column 15, lines 39-68 and Column 16, lines 1-58. There are no Figures in Stylli illustrating the structure or features of the nanoliter dispensers and no Figures illustrating their relationship to other aspects of the modules of Stylli.

In Stylli, there is no electronic communication between a nanoliter dispenser (of the sample distribution module) and its reservoir from which it receives fluid, and therefore fails to disclose Applicant's claimed method in which the consumable cartridge is removably received into the test apparatus to enable fluid communication and electronic communication with a drop-on-demand printhead.

In addition, the nanoliter dispensers in Stylli (and any reservoir associated with or forming a part of the nanoliter dispensers) are not replaceable. Rather, the nanoliter dispensers in Stylli form a permanent part of liquid handler and the sample distribution module, and therefore are not replaceable and are not removably receivable within a test system, as claimed by Applicant. Moreover, the reservoirs described as part of or in cooperation with the nanoliter dispensers are not replaceable. Accordingly, the nanoliter dispensers of Stylli do not describe or suggest Applicant's claimed method of removably receiving into a test apparatus at least one consumable cartridge for containing at least one potential pharmaceutically active agent.

In Applicant's claimed method, the consumable cartridge allows disposal of the cartridge after depletion of agent from the chamber (e.g., reservoir) of cartridge – permitting a single use of the cartridge. This feature helps to maintain sterility of the test apparatus and avoid time-consuming cleaning operations of reservoirs, as would be necessary with the reservoirs of the nanoliter dispensers of Stylli. See Stylli at Col. 16, lines 52-58. Accordingly, in Applicant's method, instead of washing out and rinsing the cartridge, prior to loading more agents/reagents into the cartridge, the empty cartridge is simply removed and a different cartridge containing an agent/reagent is inserted into the test apparatus for fluid communication with the printhead to enable faster resumption of testing. Moreover, the feature of removably receiving the cartridge into the test apparatus permits removing the cartridge even prior to exhaustion of the agent from the chamber so that a different cartridge having a second agent can be inserted into the test apparatus. Accordingly, one can switch agents being dispensed without having to perform a cleaning operation of the cartridge, and one can do so before the chamber (in fluid communication with the printhead) is emptied. Stylli fails disclose such removable reception and/or consumability of its nanoliter dispensers, and particularly their reservoirs.

Applicant's specification describes the replaceable/consumable feature and the removable receiving of these cartridges into the test apparatus at page 6, paragraph 16; page 11, paragraph 39; page 13, paragraphs 44 and 45; and page 17, paragraph 60. Figures 2 and 3 also illustrate the ability to removably receive the replaceable/consumable cartridges.

In addition, Stylli discloses a reaction module, referring to a second reagent dispenser and generally discloses having multiple dispenser with different reagents. However, at no time does Stylii disclosing dispensing a first defined volume onto target cellular material and then, based upon generated information about the pharamacologic effect of the first defined volume, interactively dispense a second defined volume onto the same target cellular material. This claimed method is significantly different than generally identifying that many different reagents can be dispensed and that many different dispensers can be used.

The cited passage in Stylli regarding a second reagent dispenser is limited to the context of the reaction module, which has a separate function and structure than either of the storage/retrieval module or the sample distribution module that has been extensively cited in the Office Actions. Stylli discloses that the reagent dispenser (of the reaction module) is of the type described in the Examples and non-specifically mentions that other reagent dispensers can be used. In the examples, Stylli alludes to several patents and publications as disclosing suitable reagent dispensers. See Stylli at Column 23, lines 20-60. Accordingly, Stylli on its faces does not disclose any details or structures of these reagent dispensers comprising a portion of the reaction module. A cursory review of the cited patents/publications within Stylli in the cited passage (Column 23, lines 20-60) reveals that they appear to disclose pipetting systems, stepper motors, piston/cylinder combinations, and pneumatic arrangements in order to dispense a fluid – none of them apparently disclosing Applicant's claimed method in which a first defined volume is dispensed from an electronically actuated drop-on-demand printhead (as part of the at least one liquid ejection device) in fluid communication and electronic communication with a replaceable cartridge.

Finally, Applicant notes that the Office Action cites Stylli as disclosing a second dispenser, when Applicant's claimed method focuses on dispensing a second defined volume (of at least one potential pharmaceutically active agent) from the same at least one liquid ejection device that is used to dispense the first defined volume (of at least one potential pharmaceutically active agent), and that the second defined volume is dispensed in an

interactive manner based on information generated from the test results of dispensing the first defined volume - - none of which is even suggested in Stylli.

For these reasons, Stylli fails to disclose Applicant's claimed automated method of analyzing substances containing cellular material, and therefore Applicant respectfully submits that Applicant's amended independent claim 41 is allowable over Stylli. Claims 42-43 are also believed to be allowable as well based on their dependency from amended independent claim 41.

CONCLUSION

In view of the above, Applicant respectfully submits that pending claims 1, 3-10, 28, 31-34, and 36-43 are in form for allowance and are not taught or suggested by the cited references. Therefore, reconsideration and withdrawal of the rejections and allowance of claims 1, 3-10, 28, 31-34, and 36-43 is respectfully requested.

No fees are required under 37 C.F.R. 1.16(b)(c). However, if such fees are required, the Patent Office is hereby authorized to charge Deposit Account No. 08-2025.

The Examiner is invited to contact the Applicant's representative at the below-listed telephone numbers to facilitate prosecution of this application.

Any inquiry regarding this Amendment and Response should be directed to either W Bradley Haymond at Telephone No. (541) 715-0159, Facsimile No. (541) 715-8581 or Paul S. Grunzweig at Telephone No. (612) 767-2504, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

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CERTIFICATE UNDER 37 C.F.R. 1.8: The undersigned hereby certifies that this paper or papers, as described herein, are being deposited in the United States Postal Service, as first class mail, in an envelope address to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 27th day of July, 2004.

By Paul S. Grunzweig
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